

K971178 RAND SURGICAL SPONGEJun 27, 1997
88 days to decisionK971178 · Product code: **EFQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k971178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal (EFQ)
Date received	Mar 31, 1997
Decision date	Jun 27, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trans Aire
Location	Sacramento, CA, US
Contact	DUANE TRACY
510(k) history	1 submissions · 1 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971178/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026